

### REMARKS

Claims 168-183 are now pending in the above-referenced patent application. Applicants respectfully request further consideration of these claims, in view of the amendments set forth above and the following remarks.

#### Amended Claims

Claims 168, 170, 171 and 178 have been amended.

Claim 168 has been amended to include the requirements of as-filed claim 171, and to clarify that the “conductance” refers to “flow conductance”.

Claim 170 has been amended to clarify that the “at least one port” recited in the claim refers to an inlet port and an outlet port of the microreactor to allow flow through the reaction cavity.

Claim 171 has been amended to require that the microcomponents each have inlet and outlet ports for fluid flow therethrough, and further that the pressure drop for each of the flow paths between the common port and each of the terminal ports is greater than the pressure drop in the microcomponent. Support for this amendment can be found in the specification, including for example at page 45, line 21 through page 46, line 6.

Claim 178 has been amended as to form, without change in the substantive scope thereof.

No new matter has been added.

#### New Claims

New claims 179-183 have been added. Support for each of these claims can be found in as-filed claim 168, considered together with the specification and drawings.

Claim 179 further requires that microfluidic fluid distribution channel is a passive microfluidic fluid distribution channel (*i.e.*, having an essential absence of active microcomponents). Support can be found, for example, at page 45, lines 29-31, also at page 59, line 23 through page 60, line 4, and further at page 91, lines 12-16.

Claim 180 requires that the manifold is provided in a substantially coplanar structure. Support can be found at page 42, lines 31-33.

Claim 181 requires that a number of preferred features, in combination, including for example that each of the flow paths between the common port and each of the terminal ports

have both (i) substantially equal conductance, and (ii) a pressure drop greater than the pressure drop across its associated microcomponent. Claim 181 also requires that the manifold is provided in a substantially coplanar structure, and that the microfluidic fluid distribution channel is a passive microfluidic fluid distribution channel. Support for this claim can be found in as-filed claims 168 and 171, and further, as described above in connection with the amendment to claim 171, and as described in connection with new claims 179 and 180.

Claim 182 is directed to a microfluidic distribution system comprising both a microfluidic fluid-supply manifold for providing fluid flow to microcomponents, and a microfluidic effluent-distribution manifold for providing fluid flow from microcomponents. Support can be found in as-filed claim 168 and in the specification, including for example at page 47, line 34 through page 48, line 3.

Claim 183 requires that the distribution channel provide simultaneous fluid communication between the common port and each of the terminal ports. Support for this amendment can be found in as-filed claim 178 and throughout the specification.

No new matter has been added.

#### Response to Restriction Requirement

The Office action sets forth a restriction requirement, and requires election between the inventions defined by Group I (claims 168-177) and Group II (claim 178).

Applicants hereby elect the claims defined by Group I (claims 168-177), with traverse.

Applicants respectfully request reconsideration of the aforementioned restriction in view of the amendments to claim 178 and the following remarks.

As amended, claim 178 clearly depends from claim 168, and therefore includes all of the requirements of claim 168. Moreover, claim 178 has been amended to require “supplying a fluid” rather than “simultaneously supplying a fluid”, thereby obviating the Office’s rationale that the apparatus can be used to practice another and materially different process other than the process claimed therein.

still stands  
app can be used  
for something else

Accordingly, the instant basis for restriction should be withdrawn.

To the extent that the Office still considers the inventions defined by independent claim 168, and claims dependent therefrom (drawn to a manifold) to be patentably distinct from the invention defined by dependent claim 178 (drawn to use of the manifold), Applicants

respectively submit that examination of all of the presently pending claims could be made without serious burden on the Examiner.

Under MPEP §803, if the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

method  
&  
app

In this case, a substantial overlap in claim requirements exists between the elected and non-elected claims. In view of such overlap of claim requirements, the search for the elected claims will necessarily include and overlap with the search for the non-elected claims. All of the presently pending claims could be searched without an undue burden on the Examiner, and therefore, restriction is improper.

Rejection Under 35 U.S.C. § 112 (Indefiniteness)

Claims 168-177 have been rejected under 35 U.S.C. §112, 2<sup>nd</sup> paragraph, as being indefinite for various reasons. (See, generally, paragraphs 8-13 at pages 3-4 of the Office action).

Applicants respectfully traverse these rejections, in view of the following remarks.

*MPEP § 2173.02*

Office policy regarding rejections under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph was recently clarified in advance of notice to changes to MPEP §2173.02 (See Memorandum from Stephen G. Kunin to Technology Center Directors dated January 17, 2003). This memorandum underscores the importance, in view of recent developments in case law, of a critical analysis as to whether a rejection under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph is warranted. In particular, it is noted that

during examination of claims for compliance with the requirement for definiteness... some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the Examiner might desire. ... (T)he Examiner must consider the claim as a whole to determine whether the claim apprises one of skill in the art of its scope, and therefore, serves the notice function required (under the statute).

See the 2<sup>nd</sup> paragraph of the Memorandum from Stephen G. Kunin to Technology Center Directors dated January 17, 2003 (emphasis added). Also, it is expressly stated that if the Examiner determines that a rejection is proper after having given such careful analysis, that

an analysis as to why the phrases(s) used in the claims is “vague and indefinite” should be included in the Office action.

See the 5<sup>th</sup> paragraph of the Memorandum from Stephen G. Kunin to Technology Center Directors dated January 17, 2003 (emphasis added).

Applicants respectfully submit that in view of the Office policy outlined above, many of the rejections made under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, in this Office action appear to completely unfounded based upon a plain reading of the claim language, and in particular based upon a reading of the claim language in the context of the specification. Also, for some of the rejections, the Office action does not set forth *any* analysis or *explanation* as to why the Examiner considers the claim language to be indefinite.

Applicants have, nonetheless, provided a detailed response to each of the issues raised by the Office with respect to this statutory requirement.

#### *Claim 168*

Specifically, with respect to claim 168, the Office action asks for clarification with respect to an alleged ambiguity regarding the value of the interger, “n”. (See paragraph 10 at page 3 of the Office action).

Applicants traverse this basis for rejection in view of the clarifying amendments to claim 168.

Applicants respectfully submit that the plain language of these claims leads to a definite understanding of what Applicants regard as their invention. Claim 168 requires a certain number of terminal ports, a certain number of channel sections, and a certain number of binary junctions, in each case the number being defined by a mathematical expression that includes an integer, “n”. The claim expressly requires that *in all embodiments*, “n” is an integer of not less than 2. The claim also requires that the manifold is further characterized by one or more additional features. In the as-amended claims, these features have been more prominently highlighted by setting them off as subparagraphs (i), (ii) and (iii). One of the potential further characterizing features – that can be applied alone or in combination with others of the characterizing features – is now designated as feature (ii), where “n” is an integer of not less than 6. Accordingly, a person of ordinary skill in the art would understand that the invention defined by claim 168 can, *in some embodiments*, be further characterized by substantially larger numbers

of terminal ports, channel sections and binary junctions, where  $n$  is not less than 6. Likewise, an ordinarily skilled artisan would understand that where others of the characterizing features are present (*e.g.*, features (i) and/or (ii)), then the number of terminal ports, channel sections and binary junctions can be characterized by their respective expressions with “ $n$ ” being an integer of not less than 2.

Such plain reading of the claim is consistent with the description of the invention as set forth in the specification and figures. *See*, for example, the specification at page 42, line 2 through page 48, line 8.

In view of the plain claim language and the extensive description relevant to this point, a person of ordinary skill in the art would be reasonably apprised as to the scope of the inventions and would understand whether or not they infringe these claims. As such, these claims are not indefinite under 35 U.S.C. § 112, second paragraph. *See United Carbon Co. v. Binney Co.*, 317 U.S. 328, 87 L. Ed. 32, 63 S. Ct. 165 (1942); *see also Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986).

#### *Claims 168-170*

Claims 168-170 are said to be incomplete for omitting essential structural cooperative relationships, specifically with regard to the connections or interrelationships among microcomponents, terminal ports, common ports, distribution channel, channel sections and binary junctions. The Office action does not, however, state with particularity which connections or interrelationships are considered to be lacking in claims 168 and 169. (*See* paragraph 11 at page 4 of the Office action). The Office action does articulate a specific concern regarding claim 170, concerning clarification for the “port” required to be in fluid communication with the reaction cavity. (*See* paragraph 12 at page 4 of the Office action).

Applicants respectfully traverse this basis for rejection, based on the following remarks, with regard to claims 168 and 169. This basis for rejection is obviated as to claim 170, in view of the amendments thereto and the following remarks.

Contrary to the assertion in the Office action, the plain language of claim 168 establishes the requisite relationship between the various structural elements. Generally, the *manifold* comprises a *common port*, a number of *terminal ports*, and a *distribution channel*. The *distribution channel* provides fluid communication between the common port and each of the

terminal ports. The *terminal ports* are adapted for fluid delivery to or fluid recovery from a corresponding number of *microcomponents*. Hence, from this, the structural interrelationship is already established between the common port, the distribution channel, the terminal ports, and the microcomponents.

The distribution channel is more specifically characterized in the claim. In particular, the claim expressly requires that the distribution channel comprise a number of *channel sections* that are *connected with each other* through a corresponding number of *binary junctions*. Hence, from this, the structural interrelationship between the distribution channel and its subcomponents – the channel sections and binary junctions – is readily apparent to a person of ordinary skill in the art.

Moreover, each of the channel sections are themselves further characterized as having at least three *access ports* – with the functionality of the access ports being to serve as the common port, as a connection port for a binary junction, or as a terminal port. This further articulates the interrelationship between the *channel sections* of the *distribution channel* and other structural features – namely the common port, the binary junctions and the terminal port.

Accordingly, a person of skill in the art would have reasonably understood that claim 168, on its face, adequately recites the connectivity and interrelationship between each required structural feature.

This is further evidenced when claim 168 is read in view of the specification. *See*, for example, the description at page 42, lines 1-22, describing a preferred embodiment in connection with Fig. 7B.

Definiteness of claim 169 is likewise demonstrated based on a plain reading of the claim language, and particularly when considered in view of the specification. *See*, for example, page 42, lines 17-22, wherein a preferred embodiment is described, with the *channel sections* being more particularly described, with reference to Fig. 7B, as including a *first channel section* (515, providing fluid communication from the common port to two binary junctions), a number of *intermediate channel sections* (516, providing fluid communication between binary junctions), and a number of *terminal channel sections* (517, providing fluid communication between a final binary junction and two terminal ports). *See also*, for example, Table 2 at page 43, line 14.

In view of the plain language of claims 168 and 169, and the substantial description relevant to this point, a person of ordinary skill in the art would be reasonably apprised as to the

scope of the inventions and would understand whether or not they infringe these claims. As such, these claims are not indefinite under 35 U.S.C. § 112, second paragraph.

Applicants also traverse this basis for rejection with regard to claim 170, in view of the amendments thereto considered in connection with the remarks below.

Claim 170 introduces the feature that the microcomponents are microreactors. As amended, the microreactors are expressly required to comprise (i) a surface that defines a reaction cavity of a certain volume, and (ii) a *microreactor inlet port* and a *microreactor outlet port*, each in fluid communication with the reaction cavity. Because a person of ordinary skill would understand the scope of this claim, this basis for rejection is obviated in connection therewith.

*Claim 171*

With regard to claim 171, the Office action queries about the meaning of the term “conductance”.

Applicants respectfully submit that this basis for rejection is obviated with respect to claim 171 in view of the amendment thereto. It is also submitted that this basis for rejection is obviated the extent that the substantive concern is extended to claim 168 – now amended to include the requirement of as-filed claim 171 – since the as-amended claim 168 refers to “flow conductance” and thereby avoids any potential lack of clarity *vis-à-vis* electrical conductivity.

Rejection Under 35 U.S.C. § 102 (Zanzucchi *et al.*)

The Office action rejects claims 168-177 under 35 U.S.C. § 102(b) as being anticipated by PCT application WO/96/15576 of Zanzucchi *et al.* (See paragraph 15 at pages 4-6 of the Office action).

Applicants respectfully traverse this basis for rejection, in view of the amendment to claim 168 and the following remarks.

As-amended, claim 168 requires that the distribution channel has a flow conductance that is substantially the same for each of the flow paths between the common port

and each of the 2<sup>n</sup> terminal ports. However, Zanzucchi *et al.* does not disclose at least this feature<sup>1</sup>.

*inherent*

The Office action asserts, with respect to the above-noted requirement regarding flow conductance, that

“(t)he channels in Figs. 1, 2, and 5 (of Zanzucchi *et al.*) appear to have binary symmetry, and therefore, the conductance of the distribution channel is substantially the same for each of the flow paths between the common portion [sic: port] and each of the terminal ports. It appears that the total flow path and change in pressure between the common port and each terminal port is the same.”

(See paragraph 15 at page 6 of the Office action). Contrary to the position stated in the Office action, however, Zanzucchi *et al.* do not disclose, teach or suggest a distribution channel with flow conductance that is substantially the same for each of the flow paths between the common port and each of the 2<sup>n</sup> terminal ports. The Examiner appears to base her conclusion on an alleged “binary symmetry” said to be shown in Figures 1, 2 and 5 of Zanzucchi *et al.* However, the presently-pending claims do not require “binary symmetry”, but rather, require flow conductance that is substantially the same for each of the flow paths between the common port and each of the 2<sup>n</sup> terminal ports. As such, even if there were some line of symmetry that could be drawn for one or more of these figures, that does not demonstrate the requirement for substantially the same flow conductance as set forth in Applicants claims.

*doesn't  
give way to  
equal flow  
conductance*

Moreover, it is readily apparent to a person of skill in the art that the flow conductance between a reagent source (e.g., 200B) and each of the reaction cells (350) of Zanzucchi would, in fact, have significantly different flow conductance. With reference to Figure 1, for example, it is readily apparent that there is a much longer flow path between the “common port” for the reagent source vessel (200B)<sup>2</sup> and a reaction cell (350) in the lower right hand corner (as shown in Fig. 1), as compared to the flow path to a reaction cell in the upper left hand corner (as shown in Fig. 1). If the lengths of the flow paths vary, there is simply no basis for asserting that the reference inherently discloses flow paths of equal conductance, absent some explicit teaching

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<sup>1</sup> Applicants disagree with many of the assertions made in the Office action about what the Zanzucchi *et al.* reference discloses and/or how such disclosure relates to Applicants invention as claimed. Applicants are not making any admissions and are not acquiescing with respect to any statement made in the Office action relating to the disclosure of the Zanzucchi *et al.* references.

<sup>2</sup> Considering the “common port”, for example, to be the point of intersection between conduit 211(B) and conduit 212(B).



that the differences in path length was compensated by some other means. The same conclusion is similarly reached upon inspection of Fig. 2 of Zanzucchi *et al.* With reference to Fig. 5, there is no basis for asserting that the equal conductance requirement of as-amended claim 168 is disclosed, since the various flow paths shown therein do not appear to originate from a common port that provides fluid communication to *each* of the terminal ports.

As such, the Office action does not demonstrate that the required feature is inherently disclosed in the Zanzucchi *et al.* reference. That is, the Office action has not established that "the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *See In re Best*, 195 USPQ 430 (CCPA 1977) (emphasis in original); *Continental Can Company USA, Inc. v. Monsanto Co.*, 20 USPQ2d 1746 (Fed. Cir. 1991); *See also Hansgirk v. Kemmer*, 40 USPQ 665, 667 (CCPA 1939) (stating that "(i)nherency may not be established by probabilities or possibilities," but rather, must be based on a "natural result flowing from the operation as taught."

Accordingly, the instant rejection under U.S.C. § 102(b) should be withdrawn.

Rejections Under 35 U.S.C. § 103(a) (Zanzucchi *et al.* and Various References)

The Office action rejects claims 168, 169 and 171-177 under 35 U.S.C. § 103(a) based on various combinations of references. Specifically, these claims have been rejected as being obvious over WO 96/15576 to Zanzucchi *et al.* in view of one to five additional references, particularly, in view of:

- U.S. Patent No. 4,537,217 to Allen, Jr., and/or
- U.S. Patent No. 4,999,102 to Cox *et al.*, and/or
- U.S. Patent No. 5,354,460 to Kearney *et al.* and/or
- U.S. Patent No. 5,938,333 to Kearney, and/or
- U.S. Patent No. 5,333,019 to Coppens.

(*See* paragraph 19 at pages 7-12 of the Office action).

Applicants respectfully traverse these rejections, in view of the amendment to claim 168 and the following remarks.

The Office action does not establish a *prima facie* case of obviousness. Preliminarily, for many of the rejections, the Office action appears to be relying on a very loose reading of what Zanzucchi *et al.* and/or the other references relied upon actually disclose, and how such

disclosure relates to the presently-pending claims. The Office action also appears, in every instance, to be clearly engaging in improper hindsight analysis.

Independent claim 168, as amended, now includes the requirements of claim 171 as previously pending, in particular that the distribution channel has a flow conductance that is substantially the same for each of the flow paths between the common port and each of the 2<sup>n</sup> terminal ports.

Admits secondary prior art

In the Office action, Allen, Jr. is said to disclose a manifold having distribution channels with a flow conductance that is substantially the same for each of the flow paths. (See paragraph 19 at page 8 of the Office action).

However, the Office action does not provide any reason as to why a person of ordinary skill in the art would have been motivated to incorporate the teaching of Allen, Jr. into the microfluidic distribution manifold of Zanzucchi *et al.* The Examiner's assertion in this regard is completely conclusory, and void of any rational that would establish obviousness. Absent some rational or motivation existing in the art, it is apparent that the Office action is improperly relying on hindsight. That is, the Office action appears to be relying on Applicants' specification to improperly extrapolate the teachings of Zanzucchi *et al.*, and to improperly combine the teachings of Zanzucchi *et al.* with arbitrarily selected portions of other references – without proper motivation for such extrapolation and combination existing in the prior art.

yes I do

In view of the repeated warnings by the Federal Circuit against hindsight reconstruction (*i.e.*, against finding the required motivation in the guidance of the instant specification), Applicants respectfully submit that such extrapolation is improper under the law. See, for example, Grain Processing Corp. v. American Maize-Products Co., 5 USPQ2d 1788 (Fed. Cir. 1988) (stating that obviousness cannot be established by merely showing that each element of the patented products may be found somewhere in the prior art). See also In re Vaeck, 20 USPQ2d 1438 (Fed. Cir. 1991), and In re Dembiczak, 50 USPQ2d, 1614 (Fed. Cir. 1999). See also In re Kotzab, 54 USPQ2d 1308 (Fed. Cir. 2000) (holding that an invention was not obvious, even though based on technologically simple concepts from a combination of known elements, since there was an absence of a specifically-identified understanding within the knowledge of a skilled artisan that would have motivated one to make the particular claimed invention).

In the present situation, there was no motivation existing in the art to combine the selected teachings of Allen, Jr. into the device disclosed in Zanzucchi *et al.* In particular, the device of

Zanzucchi *et al.* is directed to a liquid distribution system said to be useful, particularly, in connection with known synthesis protocols for biopolymers (*e.g.*, peptides, proteins, oligonucleotides, DNA, *etc.*). Such synthesis protocols include step-wise coupling of bio-monomers (*e.g.*, amino acids or nucleic acids), where the diversity of such biopolymers is achieved by sequentially varying the supply of reagents to the reaction cells for stepwise coupling – with such supply being accomplished through the fluid distribution system of Zanzucchi *et al.* Significantly, in such synthesis protocols, the amount of a reagent delivered to a particular reaction cell in total and/or the amount of reagent delivered to a particular reaction cell over a particular period of time (*e.g.*, flow rate) was not of a significant concern, since the sequential reaction steps (deprotect – couple – protect) for biopolymer synthesis were typically run with excess reagents. Accordingly, a person of skill in the art would not have been motivated to modify Zanzucchi *et al.* to provide for flow paths of “equal conductance”. The benefit of such feature –being able to passively provide reagents to the microcomponents in controlled amounts and/or at controlled flow rates – was simply not needed in connection with the type of chemistries for which Zanzucchi *et al.*’s flow distribution system was designed and used.

Moreover, the embodiment of Zanzucchi *et al.* includes numerous active flow-control elements to provide for selective control and delivery of fluid reagents from the reactant sources to each of the reaction cells. [The Office action does not address *why*, in view of such existing active control elements, a person of ordinary skill in the art would modify Zanzucchi to use a manifold having equal flow conductance, such as disclosed by Allen, Jr.]

Further, an artisan of ordinary skill would recognize substantial differences in scale between the microreactors of Zanzucchi *et al.* and the flow distribution system of Allen, Jr. [The Office action does not, however, address *why* a person of ordinary skill in the art would overlook such differences in scale in connection with combining features from Allen, Jr. into Zanzucchi *et al.*]

Finally, an artisan of ordinary skill would not have been motivated to modify the fluid distribution system of Zanzucchi *et al.* by simply substituting therein the manifold disclosed by Allen, Jr., since such modification would have rendered the Zanzucchi *et al.* array unsuitable for its intended purpose. That is, if the fluid flow were effected in Zanzucchi *et al.* using the manifold of Allen, Jr., this would not provide for *selective distribution* of reagents to only some of the reaction cells but not others, as required for stepwise coupling reactions for biopolymer synthesis. It is well

settled that no suggestion or motivation can be established for proposed modifications to a prior art embodiment, where such modifications would render the prior art embodiment unsuitable or unsatisfactory for its intended purpose. *See* MPEP 2143.02; *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984).

As such, for at least the aforementioned reasons, as-amended claim 168 would not have been obvious over the combination of Zanzucchi *et al.* and Allen, Jr. The same arguments apply equally as well with respect the other art relied upon in the Office action. Specifically, none of Cox *et al.* ('102), Kearney *et al.* ('460), Kearney ('333) or Coppens ('019), considered alone or in combination, are more relevant to the instant discussion than Allen, Jr.<sup>3</sup>

Further, Coppens ('019) is not prior art to Applicants' invention under 103(a)/102(e), since the effective filing date for the instant application is March 3, 1999. That is, the instant application is a divisional application of U.S. Serial No. 09/518,794, filed March 3, 2000, which itself claims the benefit of U.S. Serial No. 60/122,704 filed March 3, 1999 by Bergh *et al.* Since the instant application has an earlier effective filing date than the filing date (April 29, 1999) of the application (Ser. No. 09/301,971) from which the '019 patent granted, said application is not prior art to Applicants invention. Also, Applicants invented the inventions defined by the presently-pending claim before the filing date (April 29, 1999) of the application (Ser. No. 09/301,971) from which the '019 patent granted. If necessary, Applicants can submit a declaration under 37 C.F.R. §1.131 as evidence thereof. Accordingly, Coppens is entitled to no consideration in connection with this basis for rejection. ] *Withdraw*

Each of claims 169 and 171-178 depend from claim 168, and are therefore patentable for at least the same reasons as stated above in connection with claim 168. Also, many of these dependent claims recite further features that have substantial commercial significance, and that are non-obvious over the art of record for further reasons.

As one example, as-amended dependent claim 171 requires that the distribution channel has a pressure drop for each of the flow paths between the common port and each of the terminal ports that is *greater than* the pressure drop across its associated microreactor. None of the art

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<sup>3</sup> Applicants disagree with many of the assertions made in the Office action about what the Allen, Jr. ('217), Cox *et al.* ('102), Kearney *et al.* ('460), Kearney ('333) or Coppens ('019) references disclose and/or how such disclosure relates to Applicants invention as claimed. Applicants are not making any admissions and are not acquiescing with respect to any statement made in the Office action relating to the disclosure of these references.

relied upon in the Office action teaches this further feature in combination with the features of claim 168. In particular, Applicants note that Allen Jr. discloses a flow distribution system that is explicitly designed to provide for extremely low pressure drop <sup>well,</sup> across the distribution channel.

[As such, even if, *arguendo*, a person of ordinary skill in the art would have modified the distribution system of Zanzucchi *et al.* to include the flow distribution manifold of Allen Jr., this would not have led to the invention defined by claim 171.]

As another example, new claim 183 requires that the distribution channel is effective for providing *simultaneous* fluid communication between the common port and each of the terminal ports. It is telling, in this regard, that the Examiner has already indicated in connection with the aforementioned restriction requirement that she regards simultaneous distribution embodiments <sup>uh?</sup> (such as that required by this claim 183) to be “materially different” from sequential distribution embodiments, such as are disclosed by Zanzucchi *et al.* for stepwise coupling reactions.

Rejections Under 35 U.S.C. § 103(a) (Zanzucchi *et al.*, Various References, and Senkan)

The Office action also rejects claim 168 based as being obvious over Zanzucchi *et al.* WO6/15576 in view of Allen, Jr. ('217), and/or Cox *et al.* ('102), and/or Kearney *et al.* ('460), and/or Kearney ('333), and/or Coppens ('019), and further in view of with U.S. Patent No. 6,426,226 to Senkan. (See paragraph 20 at page 12 of the Office action).

This basis for rejection is respectfully traversed.

U.S. Patent No. 6,426,226 to Senkan, does not constitute prior art to Applicants' invention. The references applied in various combinations with the Senkan '226 patent do not disclose or suggest each of the required features of Applicants' inventions as-claimed, as described above. Therefore, the Office action does not establish a *prima facie* case of obviousness.

Applicants respectfully submit that U.S. Patent No. 6,426,226 to Senkan does not constitute prior art to Applicants' invention under 35 U.S.C. § 102(e). As identified on the front page of the '226 patent to Senkan, and as illustrated on the “timeline” sketch attached as Appendix 1 of this response, the application from which Senkan's '226 patent granted was filed on October 27, 2000 (as U.S. Ser. No. 09/697,162). As discussed in detail below, Applicants submit that this date – October 27, 2000 – is the effective 102(e) date for this reference, and that Senkan is not entitled to the benefit of its earlier-filed applications for purposes of establishing a

§ 102(e) date. Since Applicants' effective filing date for the instant application is the filing date of its parent application – March 3, 2000, and since the parent itself claims the benefit of an earlier-filed provisional application having a priority date of March 3, 1999, the Senkan reference is not prior art to the instant application.

Recent changes to the law regarding 35 U.S.C. § 102(e) have clarified the analysis for determining when an application of one inventive entity can be prior art to another applicant. More specifically, amendments made to 35 U.S.C. § 102(e) by H.R. 2215 (“Technical Amendment Act”) enacted November 2, 2002 and retroactively effective as of November 29, 2000 have resulted in an analysis that is applied to all pending applications regardless of the filing date of the application, and therefore applies to the instant application. Significantly, the law is clear that U.S. patent applications that are derived from or claim priority to international applications (*e.g.*, PCT applications) may be applied as prior art as of the effective date of the *international application* if and only if all of the following three conditions are met: (i) the filing date of the international application is on or after November 29, 2000; (ii) the international application designated the U.S. and (iii) the international application was published in English. If one of these conditions is not met, then the effective filing date for § 102(e) purposes is the filing date of the actual U.S. application – not the filing date of the international application.

In the current situation, the application from which Senkan's '226 patent granted was filed on October 27, 2000 (as U.S. Ser. No. 09/697,162). This application is said to be a continuation of an international PCT application filed on November 11, 1999 (as PCT/GB99/03767). The PCT application itself is said to be a continuation of an earlier-filed U.S. application filed November 12, 1998 (as U.S. Ser. No. 09/191,849), subsequently abandoned.<sup>4</sup> However, since the international PCT application from which Senkan's 09/697,162 application claims priority was filed before November 29, 2000, the filing date of the international PCT application cannot be applied as the effective § 102(e) filing date for the Senkan '226 application.

This situation is discussed in a PTO Memorandum dated November 4, 2002 from Stephen G. Kunin to Technology Center Directors, a copy of which is attached hereto as

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<sup>4</sup> Further earlier-filed applications are also present in the priority claim, but are irrelevant in connection with the present analysis, and discussion thereof is therefore omitted for the sake of brevity and clarity.

Appendix 2. Moreover, Examination Guidelines published by the PTO, a copy of which is attached as Appendix 3, further illustrate this situation. (See Example 9 at page 17 thereof.) See also, the PTO's website at

[http://www.uspto.gov/web/offices/dcom/olia/aipa/102e\\_hr2215slides.pps](http://www.uspto.gov/web/offices/dcom/olia/aipa/102e_hr2215slides.pps)

which provides a slide presentation prepared by Robert J. Spar dated November 14, 2002 regarding the changes under H.R. 2215. This slide presentation demonstrates an exactly analogous situation in one of the slides, a copy of which is included as Appendix 4 hereof.

Since the application leading to the Senkan '226 patent is not prior art to the instant invention, these bases for rejection are obviated. Additionally, and independently, Applicants submit that even if the Senkan reference were prior art, it does not make the invention defined by the aforementioned claims obvious, either alone or in the various combinations set forth in the Office action, since it does not disclose all of the required features thereof.<sup>5</sup>

As such, the Office action does not set forth a *prima facie* case of obviousness with respect to the aforementioned rejections. Accordingly, Applicants respectfully request that these basis for rejection be withdrawn.

Rejections Under 35 U.S.C. § 103(a) (Zanzucchi *et al.*, Various References, and Bard)

The Office action rejects claim 170 based as being obvious over Zanzucchi *et al.* WO6/15576 in view of Allen, Jr. ('217), and/or Cox *et al.* ('102), and/or Kearney *et al.* ('460), and/or Kearney ('333), and/or Coppens ('019), and further in view of with U.S. Patent No. 5,580,523 to Bard. (See paragraph 21 at page 13 of the Office action).

This basis for rejection is respectfully traversed.

Claim 170 depends from claim 168, and is therefore patentable over Zanzucchi *et al.* WO6/15576 in view of Allen, Jr. ('217), and/or Cox *et al.* ('102), and/or Kearney *et al.* ('460), and/or Kearney ('333), and/or Coppens ('019) for the same reasons as articulated above. Bard ('523) does not make up for the deficiencies noted above for establishing a *prima facie* case of obviousness for claim 168 and claims depending therefrom.

Accordingly, this basis for rejection should be withdrawn.

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<sup>5</sup> Applicants disagree with many of the assertions made in the Office action about what the Senkan '226 reference discloses and/or how such disclosure relates to Applicants invention as claimed. Applicants are not making any admissions and are not acquiescing with respect to any statement made in the Office action relating to the disclosure of the Senkan '226 patent.

Provisional Rejection Under 35 U.S.C. § 103(a)/102(e) (Copending US 09/518,794)

The Office action provisionally rejects claims 168-177 under 35 U.S.C. § 103(a)/102(e) as being obvious over co-pending application, U.S. Ser. No. 09/518,794. (See paragraph 22 at pages 13-14 of the Office action).

Applicants respectfully submit that the aforementioned copending application is not prior art under 35 U.S.C. § 103(a)/102(e) since, contrary to the assertion in the Office action, it does not have an earlier effective filing date than the instant application. The instant application is a divisional application of the cited reference application, Serial No. 09/518,794, filed March 3, 2000, which itself claims the benefit of U.S. Serial No. 60/122,704 filed March 3, 1999.

Since both the referenced application and the instant application have the same effective filing date, the cited reference is, therefore, not prior art under 35 U.S.C. § 103(a)/102(e). Accordingly, this basis for rejection should be withdrawn.

Provisional Obvious-Type Double-Patenting (U.S. Serial No. 09/518,794)

Claims 168-177 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 20, 26-28, 61 and 92-96 of copending Application Serial No. 09/518,794. (See paragraph 23 at page 14 of the Office action). The same basis for rejection appears to repeated a second time, apparently erroneously. (See paragraph 25 at page 15 of the Office action).

Applicants will consider submitting a terminal disclaimer to obviate the provisional rejection, if necessary, once agreement is reached on remaining substantive issues.

New Claims 179-182 are Patentable over the Art of Record

Applicants submit that the new independent claims are likewise novel and non-obvious over Zanzucchi *et al.* Patentability of these claims is readily established over Zanzucchi *et al.*, considered alone or in combination with the art of record.

In particular, for example, Zanzucchi *et al.* does not disclose, teach or suggest a distribution manifold having a passive fluid distribution channel (claim 179). Rather, each embodiment of Zanzucchi *et al.* explicitly discloses valving and other active flow-control elements. the manifold in is a passive microfluidic fluid distribution channel (*i.e.*, having an



essential absence of active microcomponents). Support can be found, for example, at page 45, lines 29-31, also at page 59, line 23 through page 60, line 4, and further at page 91, lines 12-16.

Moreover, Zanzucchi *et al.* does not disclose, teach or suggest a distribution manifold that is provided in a substantially coplanar structure (claim 180). The Office action posits, in this regard, that

“the channel sections of the distribution channel (of Zanzucchi *et al.*) are substantially coplanar, as parts of the channels would be coplanar.”

(See paragraph 15 at page 6 of the Office action). However, even if it were true that a single plane could be established that cuts through at least *some components* of the distribution channels of Zanzucchi *et al.*, this does not anticipate the distribution manifold of claim 180 – which requires that common port, terminal ports and distribution channel of the manifold are in a substantially coplanar structure. This requirement is clearly not disclosed by Zanzucchi *et al.*, as is readily evident to a person of ordinary skill based on inspection of the figures thereof.

Further, claim 181 is clearly patentable over Zanzucchi *et al.* This claim requires features that have already been demonstrated as novel (discussed above) in combination, so that the distribution manifold defined by this claim is provided in a substantially coplanar structure, includes a passive microfluidic fluid distribution channel, and has flow paths characterized by both substantially equal conductance, and a pressure drop greater than the pressure drop across its associated microcomponent.

Finally, Zanzucchi *et al.* do not disclose a microfluidic distribution system comprising both a microfluidic fluid-supply manifold for simultaneously providing fluid flow to microcomponents, and a microfluidic effluent-distribution manifold for simultaneously recovering fluid flow from microcomponents, as defined in claim 182.

Accordingly, favorable consideration of these new independent claims is likewise requested.

### Equivalents

The amendments to the claims and the arguments presented in supplemental response to the Office action have been made to claim subject matter which the Applicants regard as their invention. By such amendments, the Applicants in no way intend to surrender any range of equivalents beyond that which is needed to patentably distinguish the claimed invention as a

whole over the prior art. Applicants expressly reserve patent coverage to all such equivalents that may fall in the range between applicants literal claim recitations and those combinations that would have been obvious in view of the prior art. In particular, as noted above, many of the amended claims (*e.g.*, claim 178) have not been narrowed within the meaning of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 62 USPQ2d 1705 (2002), and Applicants are therefore entitled to the full range of equivalents with respect to each of the presently-pending claims.

Information Disclosure Statement

An Information Disclosure Statement is being filed on the date even herewith listing newly cited references. Consideration of the pending claims is respectfully requested, in particular, in view of the newly cited references.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

The Examiner is hereby authorized to charge the fees required in connection with this Amendment B to Deposit Account No. 50-0496, in accordance with the Transmittal submitted herewith. The Examiner is also authorized to debit any other fees required in connection with this application, or to credit any overpayment of fees in connection with this application to Deposit Account No. 50-0496.

Respectfully submitted,

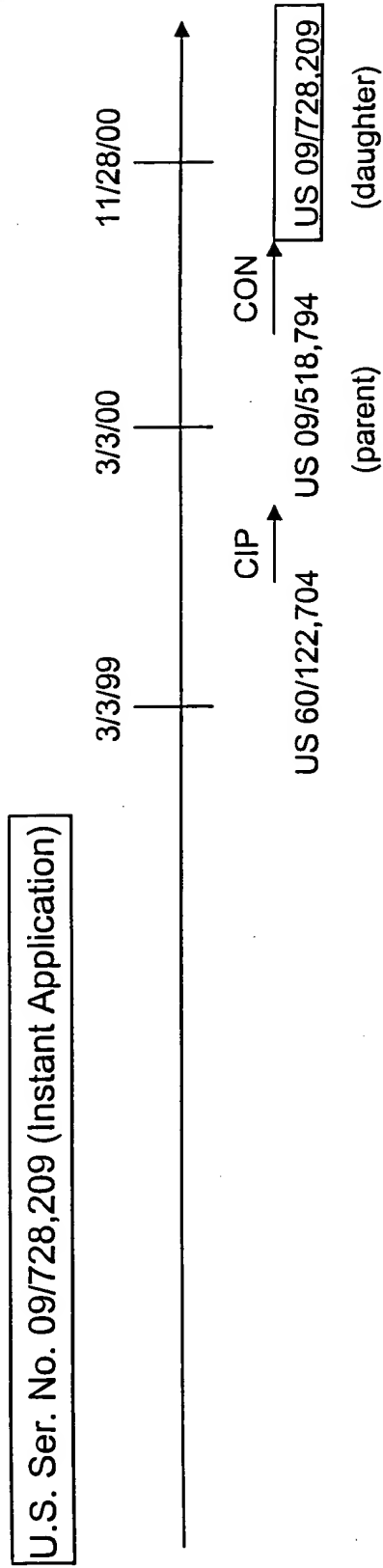
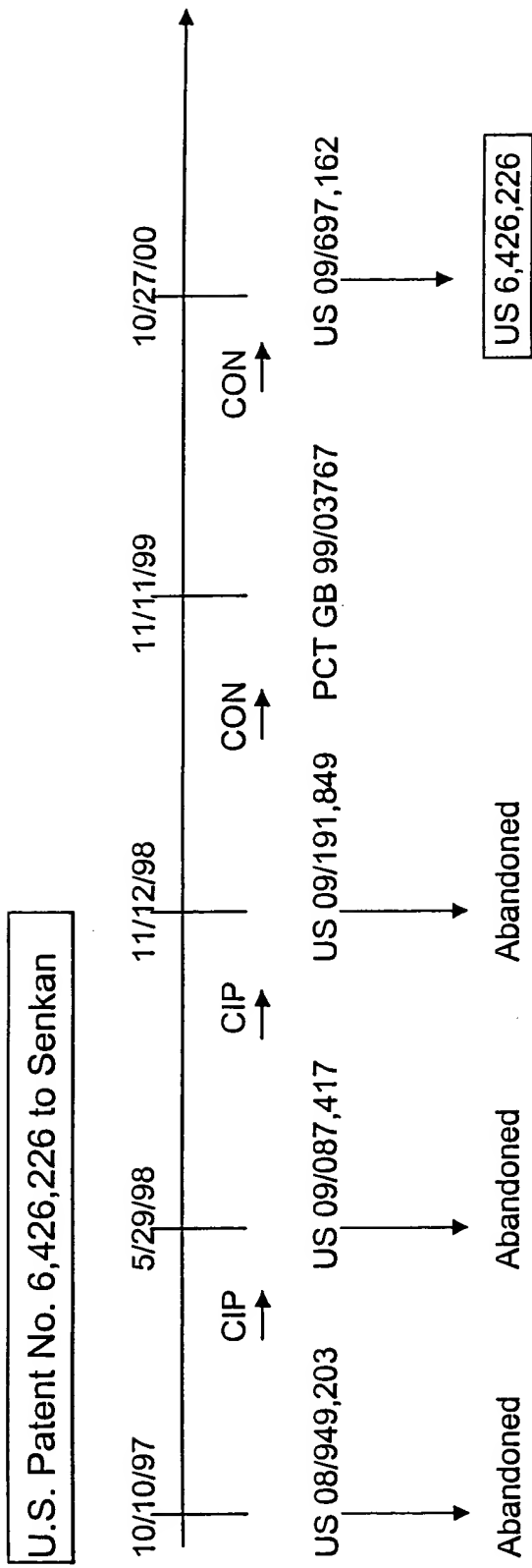


Date Submitted: Sep. 24, 2003

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# APPENDIX I





## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

MEMORANDUM

**DATE:** November 4, 2002

**TO:** Technology Center Directors

**FROM:** Stephen G. Kunin  
Deputy Commissioner for Patent Examination Policy

**SUBJECT:** Revision to 35 U.S.C. § 102(e)

**Summary:** The recently enacted amendments to 35 U.S.C. § 102(e) make several changes to determining prior art under § 102(e). The revised provisions allow the use of certain WIPO and U.S. application publications and certain U.S. patents as prior art under 35 U.S.C. § 102(e) as of their respective U.S. filing dates, including certain international filing dates. The revised provisions in 35 U.S.C. § 102(e) are completely retroactive and, **effective immediately, must always** be applied in making patentability determinations in any application being examined or patent being reexamined. Thus, the newly amended § 102(e) completely nullifies the changes to § 102(e) made by the AIPA. Accordingly, the filing date of the application being examined (or patent being reexamined) no longer determines which version of 35 U.S.C. § 102(e) is used. The disclosure of an application that is issued as a U.S. patent, or published as a U.S. application publication, or a WIPO publication of an international (PCT) application (IA), will be applied as prior art as of the same prior art date unless the application is an IA filed before November 29, 2000, or it claims the benefit of the filing date of an IA filed before November 29, 2000.

**Prior Art Dates:**

**Non-IA U.S. filing dates as prior art dates:** U.S. application publications and U.S. patents, that did **not** result from the national stage of an IA (*i.e.*, did not result from a 35 U.S.C. § 371 application) and that do **not** claim the benefit of a prior IA, may be applied as prior art as of the actual filing date under 35 U.S.C. § 111(a), or any filing date claimed under 35 U.S.C. §§ 119(e) or 120\*.

**IA filing dates as prior art dates:** The most significant change to 35 U.S.C. § 102(e) is that certain IA filing dates are U.S. filing dates for prior art purposes. U.S. and WIPO application publications and U.S. patents, which are derived from IAs or claim the benefit of IA filing dates\* (per 35 U.S.C. § 365(c)), may be applied as prior art as of the IA filing dates but only if all of the following conditions are true:

- The international filing date is: **on or after November 29, 2000;**
- The IA **designated the U.S.;** and
- The IA was **published in English.**

If an IA meets the above conditions, a further claim of benefit in the IA will enable the prior art date to be any date claimed under 35 U.S.C. §§ 119(e), 120, or 365(c)<sup>1\*</sup>.

\* Use of the earlier application's filing date is appropriate only if the relied upon application(s) supports the subject matter used to make the rejection. See MPEP 2136.03 parts III and IV.

**The Exception:** Patents issued from IAs filed prior to **November 29, 2000** may be applied as of the date of compliance with 35 USC § 371(c)(1), (2) and (4). U.S. application publications and WIPO publications of IA's filed prior to **November 29, 2000** may not be applied as of the IA filing date or the § 371(c)(1),(2) and (4) date.

**Foreign priority:** While applications that have been published as U.S. or WIPO application publications, or patented in the U.S., may have proper priority claims to foreign applications per 35 U.S.C. §§ 119(a)-(d) or 365(a), the foreign applications' filing dates may never be used as the prior art dates of such publication or patent references. This would, similarly, preclude usage of international filing dates when they are claimed as foreign priority dates under 35 U.S.C. § 365(a).

#### **Implementation Issues:**

**Final rejection practice:** If a second or subsequent action contains a new ground of rejection necessitated by the change to 35 U.S.C. § 102(e) that was not also necessitated by an amendment to the claims or as a result of certain information disclosure statements (See MPEP 706.02(a)), that action cannot be made final. See MPEP 706.07(a).

**Implementation Materials:** To help examiners understand the revised provisions of § 102(e), and to facilitate the transition to the examination practices to be followed now that the revised § 102(e) is always applicable, the following materials are being provided:

- Appendix I: Examination Guidelines (O.G. Notice)
- Appendix II: Training slides with a number of examples
- Appendix III: Flowchart to determine prior art applicability
- Appendix IV: Revised Form Paragraphs (e-version to be available prior to OACS revision)

The MPEP and the form paragraphs in OACS shall be revised to adopt these materials in due course.

**Further Assistance:** Contact Rob Clarke (305-9177), Senior Legal Advisor, or Jeanne Clark (306-5603), Legal Advisor, OPLA, if you have any questions or desire assistance for special circumstances. Alternately, you may send an e-mail to "Patent Practice", the OPLA e-mail address that has been established for receiving queries and questions about patent practice and procedures.

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<sup>1</sup> If the parent and child applications are IAs, both of the IAs must satisfy the three conditions to be applied as of the earlier IA filing date.

**Examination Guidelines for 35 U.S.C. § 102(e), as amended by the American Inventors Protection Act of 1999, and further amended by the Intellectual Property and High Technology Technical Amendments Act of 2002, and 35 U.S.C. § 102(g)**  
(Revised <sup>1</sup>)

This notice sets forth the interpretation by the United States Patent and Trademark Office (USPTO or Office) of 35 U.S.C. §§ 102(e) and 374, as amended by the American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106-113, 113 Stat. 1501 (1999)), and as further amended by the Intellectual Property and High Technology Technical Amendments Act of 2002 (H.R. 2215) (Pub. L. 107-273 (2002)). This notice also clarifies the Office's policy on prior art rejections based on 35 U.S.C. § 102(g).

Generally, 35 U.S.C. § 102(e), after enactment of the AIPA and H.R. 2215, is similar to the pre-AIPA § 102(e), with two significant differences, which may be summarized as: (1) in addition to U.S. patents, now certain **publications** of U.S. and international applications may be applied as of their filing dates in a prior art rejection; and (2) **certain international filing dates** are now U.S. filing dates for prior art purposes under § 102(e), and U.S. patents and certain application publications may now be applied as of these international filing dates in a prior art rejection.

Specifically, this notice provides guidance that prior art, as defined by § 102(e) of the patent code in effect on November 29, 2000, includes U.S. patents, publications of U.S. patent applications and World Intellectual Property Organization's (WIPO) publications of international applications, provided such references do not directly or indirectly result from an international application filed before November 29, 2000. If a U.S. patent resulted from an international application filed before November 29, 2000, the U.S. patent will have a prior art date per § 102(e) in effect prior to November 29, 2000, which is the earlier of the date of compliance with § 371(c)(1), (2) and (4) of the patent code (e.g. National Stage entry) or the filing date of the later-filed U.S. application that claimed the benefit of the international application. A U.S. or WIPO publication of an international application filed prior to November 29, 2000 will have no prior art effect under § 102(e). Such publications do, however, have prior art effect under § 102(a) or (b) as of their publication dates.

Furthermore, all pending U.S. patent applications being examined, and all U.S. patents being reexamined, or otherwise being contested, whenever filed, are subject to the amended version of § 102(e).

This notice also provides examples of the determination of § 102(e) dates for references based on the most common factual scenarios. The examples that best highlight the recent change to §§ 102(e) and 374 are the examples that involve a WIPO publication of an international application under PCT Article 21(2), a U.S. publication of an international application, or a U.S. patent derived from an international application.

The policy and practice set forth in the Official Gazette Notice entitled "Examination Guidelines for 35 U.S.C. § 102(e)(2), as amended by the American Inventors Protection Act of 1999," 1243 O.G. 1037 (Feb. 27, 2001) and guidelines provided in the Manual of

Patent Examining Procedure (MPEP) concerning the changes made by the AIPA to 35 U.S.C. § 102(e) (e.g., MPEP 706.02(a), Part II; 901.03; 1895.01, Part E; 1896; and 2136 et seq., Eighth Edition (August 2001)) are superceded by this notice and should no longer be followed.

### SIGNIFICANT PROVISIONS:

#### **A. Effective Date Provisions of the Amendments.**

The technical correction legislation in H.R. 2215 provides for the application of revised 35 U.S.C. § 102(e) in the examination of all applications, whenever filed, and the reexamination of, or other proceedings to contest, all patents. The filing date of the application is no longer relevant in determining what version of § 102(e) to apply in determining the patentability of that application, or the patent resulting from that application. The revised statutory provisions supercede all previous versions of §§ 102(e) and 374, with only one exception, which is when the potential reference is based on an international application filed prior to November 29, 2000 (discussed further in section D below). Furthermore, the provisions amending §§ 102(e) and 374 in H.R. 2215 are completely retroactive to the effective date of the relevant provisions in the AIPA (November 29, 2000).

#### **B. U.S. and WIPO application publications may have a § 102(e)(1) prior art date.**

Paragraph (e) of 35 U.S.C. § 102 was amended by the AIPA to create two separate clauses, namely, § 102(e)(1) for **publications** of patent applications and § 102(e)(2) for patents. Section 102(e)(1), in combination with amended § 374, created a new category of prior art by providing prior art effect for certain **publications** of patent applications, including international applications, as of their effective United States filing dates (which will include certain international filing dates). Under H.R. 2215's revised § 102(e), an international filing date, which is on or after November 29, 2000, is a United States filing date for prior art purposes under 35 U.S.C. § 102(e) if the international application designated the United States and was published by the World Intellectual Property Organization (WIPO) under the Patent Cooperation Treaty (PCT) Article 21(2) in the English language. Publication under PCT Article 21(2) may result from a request for early publication by an international applicant or after the expiration of 18-months after the earliest claimed filing date in an international application. An applicant that has designated only the U.S. would continue to be required to request publication from WIPO as the reservation under PCT Article 64(4) continues to be in effect for such applicants.

#### **C. A patent from an international application may have a § 102(e)(2) prior art date of its international filing date.**

Paragraph (e) of 35 U.S.C. § 102 was also amended by the AIPA to eliminate the reference to fulfillment of the 35 U.S.C. § 371(c)(1), (2) and (4) requirements. As a result, United States **patents** issued directly from international applications filed on or after November 29, 2000 will no longer be available as prior art under § 102(e) as of the date the requirements of § 371 (c)(1), (2) and (4) have been satisfied. Under § 102(e)(2), as amended by the AIPA and H.R. 2215, an international filing date, which is on or after November 29, 2000, is a United States filing date for purposes of determining the earliest

effective prior art date of a patent if the international application designated the United States and was published in the English language under PCT Article 21(2) by WIPO.

**D. International filing dates prior to November 29, 2000 cannot be used under § 102(e) for prior art purposes.**

No international filing dates prior to November 29, 2000 may be relied upon as a prior art date under § 102(e) in accordance with the last sentence of the effective date provisions (reproduced below in section I). **Patents** issued directly, or indirectly, from international applications filed before November 29, 2000 may only be used as prior art based on the provisions of § 102(e) in effect before November 29, 2000. Thus, the date of such a prior art patent is the earliest of the date of compliance with 35 U.S.C. § 371(c)(1), (2) and (4), or the filing date of the later-filed U.S. continuing application that claimed the benefit of the international application. **Publications** of international applications filed before November 29, 2000 (which would include WIPO publications and U.S. publications of the National Stage (§ 371)) do not have a § 102(e) date at all. Specifically, under § 374, the international application must be filed on or after November 29, 2000 for its WIPO publication to be “deemed a publication under section 122(b)” and thus available as a possible prior art reference under § 102(e) as amended by the AIPA.

**E. Additional requirements for international applications filed on or after November 29, 2000.**

If an international application was filed on or after November 29, 2000, the international application must have **designated the U.S.** and been **published in English** under PCT Article 21(2) by WIPO in order for its international filing date to be a U.S. filing date for purposes of § 102(e) and be relied upon as a prior art date.

**F. When an international application cannot serve as a bridge to an earlier-filed application.**

International applications, which: (1) were filed prior to November 29, 2000, (2) did not designate the U.S., or (3) were not published in English under PCT Article 21(2) by WIPO, may not be used to reach back (bridge) to an earlier filing date through a priority or benefit claim for prior art purposes under 35 U.S.C. § 102(e).

**DISCUSSION:** Sections I – V below set forth the USPTO’s examination procedures for the amendments to 35 U.S.C. § 102(e) made by the AIPA and H.R. 2215.

**I) Statutory Language of 35 U.S.C. §§ 102(e) and 374:**

*Pre-AIPA § 102(e): Now, only applies to Patents derived from International Applications filed before November 29, 2000:*

“A person shall be entitled to a patent unless —

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the



requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by applicant for patent, or”.

*Revised § 102(e): For examining all Applications, whenever filed, and for reexamining of all Patents, and for determining the prior art dates<sup>2</sup> of Patents and certain Application Publications:*

A person shall be entitled to a patent unless  
 (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or

*Pre-AIPA § 374: For WIPO Publications of International Applications filed prior to November 29, 2000:*

The publication under the treaty of an international application shall confer no rights and shall have no effect under this title other than that of a printed publication.

*Revised § 374: For WIPO Publications of International Applications filed on or after November 29, 2000:*

The publication under the treaty defined in section 351(a) of this title, of an international application designating the United States shall be deemed a publication under section 122(b), except as provided in sections 102(e) and 154(d) of this title.

*Effective Date Provisions for the amendments to §§ 102(e) and 374<sup>3</sup>, as amended by H.R. 2215:*

Except as otherwise provided in this section, sections 4502 through 4504 and 4506 through 4507, and the amendments made by such sections, shall be effective as of November 29, 2000, and shall apply only to applications (including international applications designating the United States) filed on or after that date. The amendments made by section 4504 shall additionally apply to any pending application filed before November 29, 2000, if such pending application is published pursuant to a request of the applicant under such procedures as may be established by the Director.

Except as otherwise provided in this section, the amendments made by section 4505 shall be effective as of November 29, 2000 and shall apply to all patents and all applications for patents pending on or filed after November 29, 2000. Patents resulting from an international application filed before November 29, 2000 and applications published pursuant to section 122(b) or Article 21(2) of the treaty defined in section 351(a) resulting from an international application filed before November 29, 2000 shall not be effective as prior art as of the filing date of the international application; however, such patents shall be effective as prior art in accordance with section 102(e) in effect on November 28, 2000.

## II) Impact of Statutory Changes and Effective Date of the Changes

As shown above, 35 U.S.C. § 102(e) has been amended to have two separate clauses, namely, **(e)(1) for publications** of patent applications, and **(e)(2) for patents**.

With respect to revised 35 U.S.C. § 102(e)(1) and 35 U.S.C. § 374, a new category of prior art is created for **publications** of patent applications. This new category includes the following two types of published patent applications:

- (1) U.S. publications of patent applications filed in the United States by another which are published under § 122(b) of title 35, United States Code; and
- (2) U.S. and WIPO publications of international applications, filed on or after November 29, 2000, by another that designated the United States and were published in the English language under PCT Article 21(2) by WIPO.

In summary, under amended §§ 102(e)(1) and 374, certain **publications** of patent applications, including certain WIPO publications of international applications (under PCT Article 21(2)) which are filed on or after November 29, 2000, are considered to be prior art as of their earliest effective United States filing date. It is important to note that a U.S. application publication of a National Stage of an international application or a WIPO publication of an **international application** under §§ 102(e)(1) and 374, as amended by H.R. 2215, can be prior art as of the international filing date if the international application had an international **filing date on or after November 29, 2000, designated the United States**, and was **published in English** under PCT Article 21(2) by WIPO. Prior to the AIPA amendments to §§ 102(e) and 374, a WIPO publication of an international application could only be prior art under § 102(a) or (b) as of the publication date (and there were no U.S. application publications).

Paragraph (e) of 35 U.S.C. § 102 was also amended to modify what U.S. **patents** are available as prior art under this subsection. Section 102(e)(2) no longer recognizes the date of fulfillment of the 35 U.S.C. § 371(c)(1), (2) and (4) requirements for prior art purposes. Section § 102(e)(2), however, considers an international filing date that is on or after November 29, 2000 as a United States filing date for purposes of determining the earliest effective prior art date of a patent if the international application designated the United States and was published in the English language under PCT Article 21(2) by WIPO.

The AIPA and H.R. 2215 also establish when the amendments to §§ 102(e) and 374 must be applied. First, the AIPA and H.R. 2215 set forth that the amendments to § 102(e) apply to all applications being examined and all patents under reexamination. See the third sentence of § 4508 of the AIPA, as amended by H.R. 2215 (addressing § 4505 of the AIPA). In other words, the revised version of § 102(e) is completely retroactive, and it applies to all applications, no matter when filed, and all patents, with only one exception, which pertains to applying, as prior art under § 102(e), patents or publications based on international applications filed prior to November 29, 2000. Further, the amendments to § 374, which “deems” certain WIPO publications of international applications under PCT Article 21(2) as U.S. publications of applications filed under 35 U.S.C. § 111(a), are only effective for international applications filed on or after November 29, 2000. Therefore, an international application must be filed on or after November 29, 2000 for its WIPO publication to be “deemed a publication under section 122(b),” and thus available as a possible prior art reference under § 102(e)(1).

### III) Prior Art Rejections based on 35 U.S.C. § 102(g)

35 U.S.C. § 102(g) issues such as conception, reduction to practice and diligence, while more commonly applied to interference matters, also arise in other contexts.

35 U.S.C. § 102(g) may form the basis for an *ex parte* rejection if: (1) the subject matter at issue has been actually reduced to practice by another before the applicant’s invention, and (2) there has been no abandonment, suppression or concealment. *See, e.g., Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1205, 18 USPQ2d 1016, 1020 (Fed. Cir. 1991); *New Idea Farm Equipment Corp. v. Sperry Corp.*, 916 F.2d 1561, 1566, 16 USPQ2d 1424, 1428 (Fed. Cir. 1990); *E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1434, 7 USPQ2d 1129, 1132 (Fed. Cir. 1988); *Kimberly Clark v. Johnson & Johnson*, 745 F.2d 1437, 1444-46, 223 USPQ 603, 606-08 (Fed. Cir. 1984). To qualify as prior art under 35 U.S.C. § 102(g), however, there must be evidence that the subject matter was actually reduced to practice, in that conception alone is not sufficient. *See Kimberly Clark*, 745 F.2d at 1445, 223 USPQ at 607. While the filing of an application for patent is a constructive reduction to practice, the filing of an application does not in itself provide the evidence necessary to show an actual reduction to practice of any of the subject matter disclosed in the application as is necessary to provide the basis for an *ex parte* rejection under 35 U.S.C. § 102(g). Thus, absent evidence showing an actual reduction to practice (which is generally not available during *ex parte* examination), the disclosure of a United States patent application publication or patent falls under 35 U.S.C. § 102(e) and not under 35 U.S.C. § 102(g). *Cf. In re Zletz*, 893 F.2d 319, 323, 13 USPQ2d 1320, 1323 (Fed. Cir. 1990) (the disclosure in a reference United States patent does not fall under 35 U.S.C. § 102(g) but under 35 U.S.C. § 102(e)).

In addition, subject matter qualifying as prior art only under 35 U.S.C. § 102(g) may also be the basis for an *ex parte* rejection under 35 U.S.C. 103. *See In re Bass*, 474 F.2d 1276, 1283, 177 USPQ 178, 183 (CCPA 1973) (in an unsuccessful attempt to utilize a 37 CFR

1.131 affidavit relating to a combination application, applicants admitted that the subcombination screen of a copending application which issued as a patent was earlier conceived than the combination). 35 U.S.C. § 103(c), however, states that subsection (g) of 35 U.S.C. § 102 will not preclude patentability where subject matter developed by another person, that would otherwise qualify under 35 U.S.C. § 102(g), and the claimed invention of an application under examination were owned by the same person or subject to an obligation of assignment to the same person at the time the invention was made. See MPEP §§ 706.02(l) and 2146 (Eighth Edition (Aug. 2001)).

For additional examples of 35 U.S.C. § 102(g) issues such as conception, reduction to practice and diligence outside the context of interference matters, see *In re Costello*, 717 F.2d 1346, 219 USPQ 389 (Fed. Cir. 1983) (discussing the concepts of conception and constructive reduction to practice in the context of a declaration under 37 CFR 1.131), and *Kawai v. Metlesics*, 480 F.2d 880, 178 USPQ 158 (CCPA 1973) (holding constructive reduction to practice for priority under 35 U.S.C. § 119 requires meeting the requirements of 35 U.S.C. §§ 101 and 112).

#### IV) Examination Procedures under 35 U.S.C. §§ 102(e) and 374

- (1) Determine the effective filing date(s) of the application being examined.  
See the Manual of Patent Examining Procedure (MPEP), sections 706.02, 1893.03(b), 1893.03(c), 1895 and 1895.01, Eighth Edition (Aug. 2001) as revised by this notice.
- (2) Determine and perform an appropriate prior art search.  
The Examiner should search for the most relevant prior art under 35 U.S.C. §§ 102 and 103, including U.S. and WIPO **publications** of patent applications, and U.S. **patents** accorded prior art dates under § 102(e).
- (3) Determine if the potential reference under § 102(e) is “by another.”  
The inventive entity of the application must be different than that of the reference in order to apply a reference under § 102(e). Note that, where there are joint inventors, only one inventor need be different for the inventive entities to be different and a rejection under § 102(e) may be applicable even if there are some common inventors. See MPEP 706.02(a), Eighth Edition (Aug. 2001) as revised by this notice.
- (4) Determine the appropriate § 102(e) date for each potential reference by following the guidelines below and examples set forth under Part V:
  - (a) The potential reference must be a U.S. patent, a U.S. application publication (35 U.S.C. § 122(b)) or a WIPO publication of an international application under PCT Article 21(2) in order to apply the reference under § 102(e).
  - (b) Determine if the potential reference resulted from, or claimed the benefit of, an international application. If the reference does, go to step (c) below.

The § 102(e) date of a reference that did not result from, nor claimed the benefit of, an international application is its earliest effective U.S. filing date, taking into consideration any proper priority or benefit claims to prior U.S. applications under §§ 119(e) or 120 if the prior application(s) properly supports the subject matter used to make the rejection. See MPEP 706.02(a), Eighth Edition (Aug. 2001) as revised by this notice.

- (c) If the potential reference resulted from, or claimed the benefit of, an international application, the following must be determined:
  - i. If the international application meets the following three conditions:
    - 1. an international filing date on or after November 29, 2000;
    - 2. designated the United States; and
    - 3. published under PCT Article 21(2) in English,
 the international filing date is a U.S. filing date for prior art purposes under § 102(e). If such an international application properly claims benefit to an earlier-filed U.S. or international application, or priority to an earlier-filed U.S. provisional application, apply the reference under § 102(e) as of the earlier filing date, assuming all the conditions of §§ 102(e), 119(e), 120, or 365(c) are met. Note, where the earlier application is an international application, the earlier international application must satisfy the same three conditions (i.e., filed on or after November 29, 2000, designated the U.S. and had been published in English under PCT Article 21(2)).
  - ii. If the international application was filed on or after November 29, 2000, but did **not** designate the United States or was **not** published in English under PCT Article 21(2), do **not** treat the international filing date as a U.S. filing date for use under 35 U.S.C. § 102(e) as a prior art date. In this situation, do **not** apply the reference as of its international filing date, its date of completion of the § 371(c)(1), (2) and (4) requirements, or any earlier filing date to which such an international application claims benefit or priority. The reference may be applied under § 102(a) or (b) as of its publication date, or § 102(e) as of any later U.S. filing date of an application that properly claimed the benefit of the international application (if applicable).
  - iii. If the international application has an international filing date prior to November 29, 2000, apply the reference under the provisions of §§ 102 and 374, prior to the AIPA amendments:
    - 1. For U.S. patents, apply the reference under § 102(e) as of the earlier of the date of completion of the requirements of § 371(c)(1), (2) and (4) or the filing date of the later-filed U.S. application that claimed the benefit of the international application.

2. For U.S. application publications and WIPO publications of international applications under PCT Article 21(2), never apply these references under § 102(e). These references may be applied as of their publication dates under § 102(a) or (b).
3. For U.S. application publications of applications that claim the benefit of an international application filed prior to November 29, 2000, apply the reference under § 102(e) as of the actual filing date of the later-filed U.S. application that claimed the benefit of the international application.
- iv. Examiners should be aware that although a publication of, or a U.S. Patent issued from, an international application may not have a § 102(e) date at all, or may have a § 102(e) date that is after the effective filing date of the application being examined (so it is not “prior art”), the corresponding WIPO publication of an international application will likely have an earlier § 102(a) or (b) date.
- (d) Foreign applications’ filing dates that are claimed (via 35 U.S.C. §§ 119(a)-(d) or 365(a)) in applications, which have been published as U.S. or WIPO application publications or patented in the U.S., may **not** be used as § 102(e) dates for prior art purposes. This would include international filing dates claimed as foreign priority dates under 35 U.S.C. § 365(a).

(5) Determine whether 35 U.S.C. § 103(c) common assignee considerations apply.

If a § 102(e) reference is applied in an obviousness rejection under 35 U.S.C. § 103(a) (including provisional rejections) in an application filed on or after November 29, 1999<sup>4</sup>, the examiner should ascertain whether there is evidence that the claimed invention and the reference were owned by the same person, or subject to an obligation of assignment to the same person, at the time the claimed invention was made. A clear statement of entitlement to the prior art exclusion by applicant(s) or a registered practitioner would be sufficient evidence to establish the prior art exclusion. A double patenting rejection, however, based on the § 102(e) reference could be applied, if appropriate, even if the reference is disqualified from being used a rejection under § 103(a). See MPEP 706.02(I), Eighth Edition (Aug. 2001).

(6) Apply the reference(s) under §§ 102 or 103, based on the provision of § 102 that gives the best prior art date for the disclosure. If a reference is prior art under both §§ 102 (a) and (e), but not § 102(b), the reference should be applied under both provisions.

- (a) Examiners should provide a copy of the appropriate statutory language under which the rejection is made in the first Office action utilizing such a rejection. Only revised (October 2002, or more current) Form Paragraphs pertaining to § 102(e) should be used.

(7) Final rejection practice: If a second or subsequent action contains a new ground of rejection necessitated by the change to 35 U.S.C. § 102(e) that was not also necessitated by an amendment to the claims or as a result of certain information disclosure statements, that action cannot be made final. See MPEP 706.07(a), Eighth Edition (Aug. 2001).

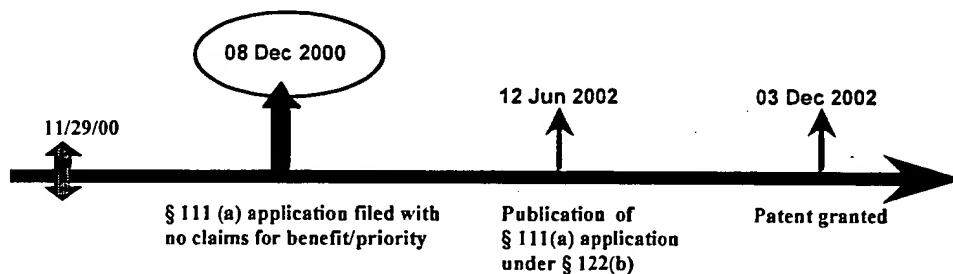
## V) Examples

In order to illustrate the prior art dates of U.S. and WIPO **publications** of patent applications and United States **patents** under § 102(e), nine examples are presented below. The examples only cover the most common factual situations that might be encountered when determining the § 102(e) date of a reference. Examples 1 and 2 involve only U.S. application publications and U.S. patents. Example 3 involves a priority claim to a foreign patent application. Examples 4-9 involve international applications. The **time lines** in the examples below show the history of the prior art **references** that could be applied against the claims of the application under examination, or the patent under reexamination.

The dates in the examples below are arbitrarily used and are presented for illustrative purposes only. Therefore, correlation of patent grant dates with Tuesdays or application publication dates with Thursdays may not be portrayed in the examples.

### Example 1: Reference Publication and Patent of § 111(a) Application with no Priority/Benefit Claims

For reference publications and patents of patent applications filed under 35 U.S.C. § 111(a) with no claim for the benefit of, or priority to, a prior application, the prior art dates under § 102(e) accorded to these references are the earliest effective United States filing date. Thus, a publication and patent of a § 111(a) application, which does not claim any benefit under either 35 U.S.C. §§ 119(e), 120 or 365(c), would be accorded the application's actual filing date as its prior art date under § 102(e).

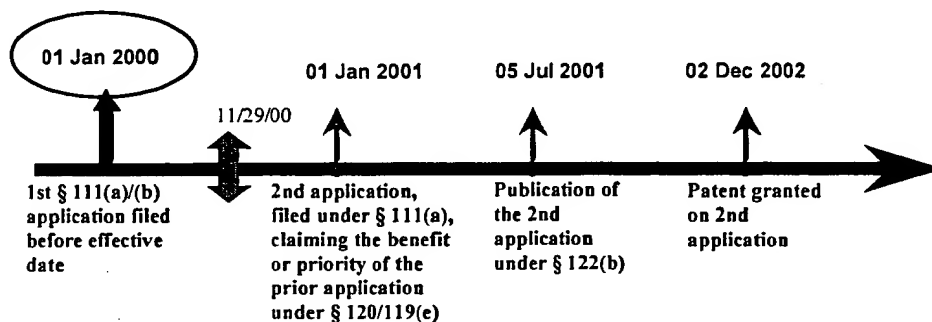


The § 102(e)(1) date for Publication is: 08 Dec 2000  
 The § 102(e)(2) date for the Patent is: 08 Dec 2000

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**Example 2:** Reference Publication and Patent of § 111(a) Application with Priority/Benefit Claim to a Prior U.S. Provisional or Nonprovisional Application

For reference publications and patents of patent applications filed under 35 U.S.C. § 111(a), the prior art dates under § 102(e) accorded to these references are the earliest effective United States filing dates. Thus, a publication and patent of a § 111(a) application, which claims priority under 35 U.S.C. § 119(e) to a prior U.S. provisional application or claims the benefit under 35 U.S.C. § 120 of a prior nonprovisional application, would be accorded the earlier filing date as its prior art date under § 102(e), assuming the earlier-filed application has proper support for the subject matter as required by §§ 119(e) or 120.



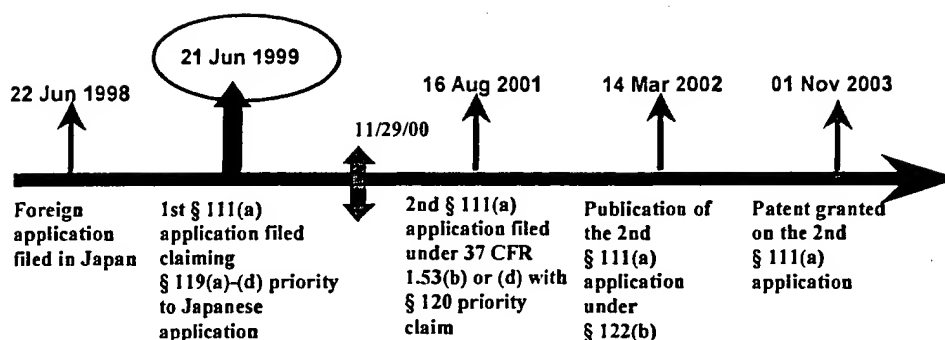
The § 102(e)(1) date for Publication is: 01 Jan 2000  
 The § 102(e)(2) date for the Patent is: 01 Jan 2000

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**Example 3:** Reference Publication and Patent of § 111(a) Application with § 119(a)-(d) Benefit Claim to a Prior Foreign Application

For reference publications and patents of patent applications filed under 35 U.S.C. § 111(a), the prior art dates under § 102(e) accorded to these references are the earliest effective United States filing dates. No benefit of the filing date of the foreign application is given under § 102(e) for prior art purposes (*In re Hilmer*, 149 USPQ 480 (CCPA 1966)). Thus, a publication and patent of a § 111(a) application, which claims benefit under 35 U.S.C. § 119(a)-(d) to a prior foreign-filed application, would be accorded its United States filing date as its prior art date under § 102(e).



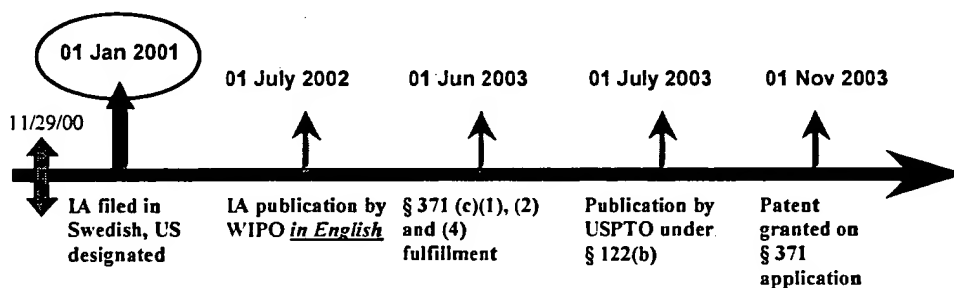


The § 102(e)(1) date for Publication is: 21 Jun 1999

The § 102(e)(2) date for the Patent is: 21 Jun 1999

**Example 4: References based on the National Stage (§ 371) of an International Application filed on or after November 29, 2000 and which was published in English under PCT Article 21(2).**

All references, whether the WIPO publication, the U.S. application publication or the U.S. patent, of an international application (IA) that was filed on or after November 29, 2000, designated the U.S., and was published in English under PCT Article 21(2) by WIPO, have the § 102(e) prior art date of the international filing date or earlier effective U.S. filing date. No benefit of the international filing date (nor any U.S. filing dates prior to the IA), however, is given for § 102(e) prior art purposes if the IA was published under PCT Article 21(2) in a language other than English.



The § 102(e)(1) date for the IA publication by WIPO is: 01 Jan 2001

The § 102(e)(1) date for Publication by USPTO is: 01 Jan 2001

The § 102(e)(2) date for the Patent is: 01 Jan 2001

**Additional Priority/Benefit Claims:**

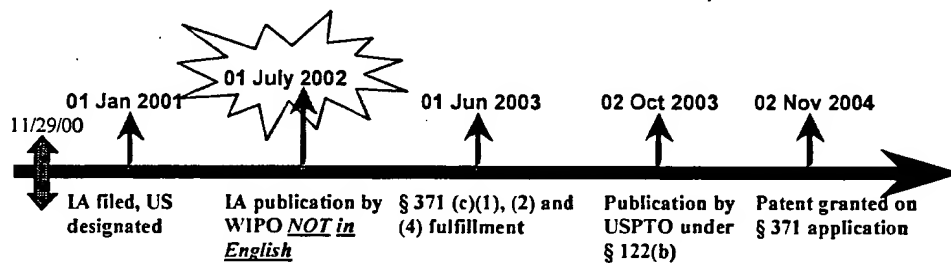
- ✓ If a later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of the IA in the example above, the § 102(e) date of the patent or publication of the later-filed U.S. application would be the international filing date, assuming the earlier-filed IA has proper support for the subject matter relied upon as required by § 120.

- ✓ If the IA properly claimed priority to an earlier-filed U.S. provisional (§ 111(b)) application or the benefit of an earlier-filed U.S. nonprovisional (§ 111(a)) application, the § 102(e) date for all the references would be the filing date of the earlier-filed U.S. application, assuming the earlier-filed application has proper support for the subject matter relied upon as required by §§ 119(e) or 120.

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**Example 5: References based on the National Stage (§ 371) of an International Application filed on or after November 29, 2000 and which was **not** published in English under PCT Article 21(2).**

All references, whether the WIPO publication, the U.S. application publication or the U.S. patent, of an international application (IA) that was filed on or after November 29, 2000 but was **not** published in **English** under PCT Article 21(2) by WIPO, have no § 102(e) prior art date at all. According to § 102(e), no benefit of the international filing date (nor any U.S. filing dates prior to the IA) is given for § 102(e) prior art purposes if the IA was published under PCT Article 21(2) in a language other than English regardless of whether the international application entered the National Stage. Such references may be applied under § 102(a) or (b) as of their publication dates, but never under § 102(e).



The § 102(e)(1) date for the IA publication by WIPO is: None

The § 102(e)(1) date for Publication by USPTO is: None

The § 102(e)(2) date for the Patent is: None

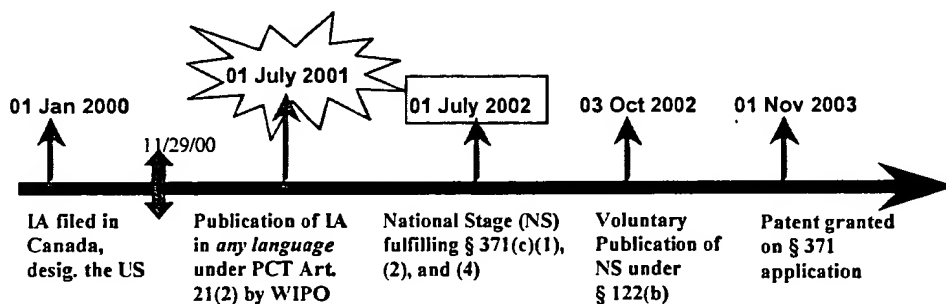
The IA publication by WIPO can be applied under § 102(a) or (b) as of its publication date (01 July 2002).

**Additional Priority/Benefit Claims:**

- ✓ If the IA properly claimed priority/benefit to any earlier-filed U.S. application (whether provisional or nonprovisional), there would still be no § 102(e) date for all the references.
  - ✓ If a later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of the IA in the example above, the § 102(e) date of the patent or publication of the later-filed U.S. application would be the actual filing date of the later-filed U.S. application.
-

**Example 6: References based on the National Stage (§ 371) of an International Application filed prior to November 29, 2000 (language of the publication under PCT Article 21(2) is not relevant)**

The reference U.S. patent issued from an international application (IA) that was filed prior to November 29, 2000 has a § 102(e) prior art date of the date of fulfillment of the requirements of 35 U.S.C. § 371(c)(1), (2) and (4). This is the pre-AIPA § 102(e). The application publications, both the WIPO publication and the U.S. publication, published from an international application that was filed prior to November 29, 2000, do not have any § 102(e) prior art date. According to the effective date provisions as amended by H.R. 2215, the amendments to §§ 102(e) and 374 are not applicable to international applications having international filing dates prior to November 29, 2000. The application publications can be applied under § 102(a) or (b) as of their publication dates.



The § 102(e)(1) date for the IA publication by WIPO is: None

The § 102(e)(1) date for Publication by USPTO is: None

The § 102(e) date for the Patent is: 01 July 2002

The IA publication by WIPO can be applied under § 102(a) or (b) as of its publication date (01 July 2001).

**Additional Priority/Benefit Claims:**

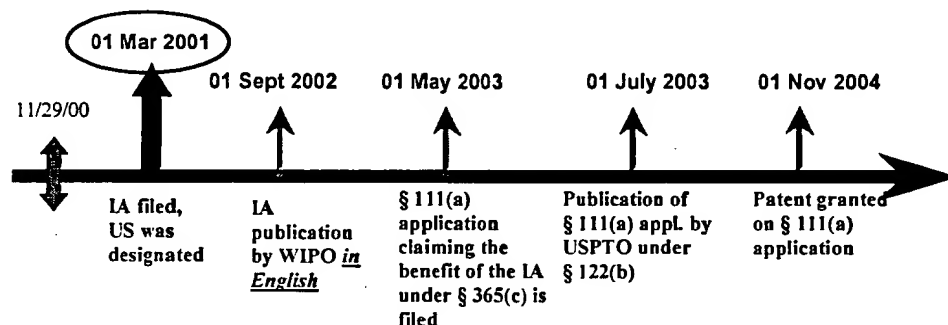
- ✓ If the IA properly claimed priority/benefit to any earlier-filed U.S. application (whether provisional or nonprovisional), there would still be no § 102(e)(1) date for the U.S. and WIPO application publications, and the § 102(e) date for the patent will still be 01 July 2002 (the date of fulfillment of the requirements under § 371(c)(1), (2) and (4)).
- ✓ If a later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of the IA in the example above, the § 102(e)(1) date of the application publication of later-filed U.S. application would be the actual filing date of the later-filed U.S. application, and § 102(e) date of the patent of the later-filed U.S. application would be 01 July 2002 (the date that the earlier-filed IA fulfilled the requirements of § 371(c)(1), (2) and (4)).
- ✓ If the patent was based on a later-filed U.S. application that claimed the benefit of the international application and the later filed U.S. application's filing date is

before the date the requirements of 35 U.S.C. 371(c)(1)(2) and (4) were fulfilled (if fulfilled at all), the 102(e) date of the patent would be the filing date of the later-filed U.S. application that claimed the benefit of the international application.

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**Example 7:** References based on a § 111(a) Application which is a **Continuation of an International Application**, which was filed on or after November 29, 2000, designated the U.S. and was published in English under PCT Article 21(2)

All references, whether the WIPO publication, the U.S. application publication or the U.S. patent of, or claiming the benefit of, an international application (IA) that was filed on or after November 29, 2000, designated the U.S. and was published in English under PCT Article 21(2) by WIPO, have the § 102(e) prior art date of the international filing date or earlier effective U.S. filing date. No benefit of the international filing date (nor any U.S. filing dates prior to the IA), however, is given for § 102(e) purposes if the IA was published under PCT Article 21(2) by WIPO in a language other than English.



The § 102(e)(1) date for the IA publication by WIPO is: 01 Mar 2001

The § 102(e)(1) date for Publication by USPTO is: 01 Mar 2001

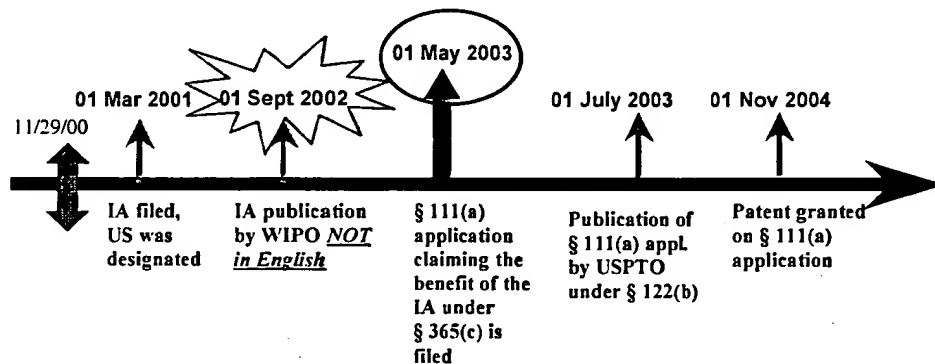
The § 102(e)(2) date for the Patent is: 01 Mar 2001

#### Additional Priority/Benefit Claims:

- ✓ If the IA properly claimed priority to an earlier-filed U.S. provisional (§ 111(b)) application or the benefit of an earlier-filed U.S. nonprovisional (§ 111(a)) application, the § 102(e) date for all the references would be the filing date of the earlier-filed U.S. application, assuming the earlier-filed application has proper support for the subject matter relied upon as required by §§ 119(e) or 120.
  - ✓ If a second, later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of the § 111(a) application in the example above, the § 102(e) date of the patent or publication of the second, later-filed U.S. application would still be the international filing date of the IA, assuming the earlier-filed IA has proper support for the subject matter relied upon as required by § 120 and 365(c).
-

**Example 8:** References based on a § 111(a) Application which is a **Continuation of an International Application**, which was **filed on or after November 29, 2000** and was **not published in English** under PCT Article 21(2)

Both the U.S. publication and the U.S. patent of the § 111(a) continuation of an international application (IA) that was filed on or after November 29, 2000 but was **not** published in English under PCT Article 21(2) by WIPO have the § 102(e) prior art date of its actual U.S. filing date under § 111(a). No benefit of the international filing date (nor any U.S. filing dates prior to the IA) is given for § 102(e) purposes if the IA was published under PCT Article 21(2) in a language other than English. The IA publication under PCT Article 21(2) does not have a prior art date under § 102(e)(1) because the IA was not published in English under PCT Article 21(2). The IA publication under PCT Article 21(2) can be applied under § 102(a) or (b) as of its publication date.



The § 102(e)(1) date for the IA publication by WIPO is: None  
 The § 102(e)(1) date for Publication by USPTO is: 01 May 2003  
 The § 102(e)(2) date for the Patent is: 01 May 2003

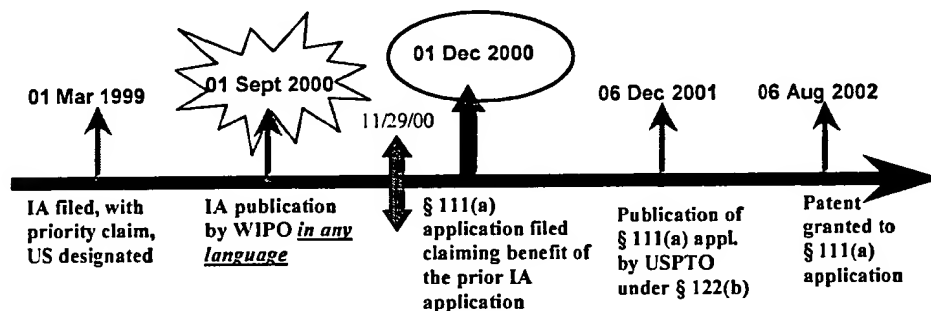
The IA publication by WIPO can be applied under § 102(a) or (b) as of its publication date (01 Sept 2002).

#### Additional Priority/Benefit Claims:

- ✓ If the IA properly claimed priority/benefit to any earlier-filed U.S. application (whether provisional or nonprovisional), there would still be no § 102(e)(1) date for the IA publication by WIPO, and the U.S. application publication and patent would still have a § 102(e) date of the actual filing date of the later-filed § 111(a) application in the example above (01 May 2003).
- ✓ If a second, later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of the § 111(a) application in the example above, the § 102(e) date of the patent or publication of the second, later-filed U.S. application would still be the actual filing date of the § 111(a) application in the example above (01 May 2003).

**Example 9:** References based on a § 111(a) Application which is a **Continuation** (filed prior to any entry of the National Stage) of an **International Application**, which was **filed prior to November 29, 2000** (language of the publication under PCT Article 21(2) is not relevant)

Both the U.S. publication and the U.S. patent of the § 111(a) continuation (filed prior to any entry of the National Stage) of an international application (IA) that was filed prior to November 29, 2000 have the § 102(e) prior art date of its actual U.S. filing date under § 111(a). No benefit of the international filing date (nor any U.S. filing dates prior to the IA) is given for § 102(e) prior art purposes if the IA was filed prior to November 29, 2000. The IA publication under PCT Article 21(2) does not have a prior art date under § 102(e)(1) because the IA was filed prior to November 29, 2000. The IA publication under PCT Article 21(2) can be applied under § 102(a) or (b) as of its publication date.



The § 102(e)(1) date for the IA publication by WIPO is: None  
 The § 102(e)(1) date for Publication by USPTO is: 01 Dec 2000  
 The § 102(e) date for the Patent is: 01 Dec 2000

The IA publication by WIPO can be applied under § 102(a) or (b) as of its publication date (01 Sept 2000).

#### Additional Priority/Benefit Claims:

- ✓ If the IA properly claimed priority/benefit to any earlier-filed U.S. application (whether provisional or nonprovisional), there would still be no § 102(e)(1) date for the IA publication by WIPO, and the U.S. application publication and patent would still have a § 102(e) date of the actual filing date of later-filed § 111(a) application in the example above (01 Dec 2000).
- ✓ If a second, later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of § 111(a) application in the example above, the § 102(e) date of the patent or publication of the second, later-filed U.S. application would still be the actual filing date of the § 111(a) application in the example above (01 Dec 2000).

FOR FURTHER INFORMATION CONTACT: Jeanne Clark or Robert Clarke, Legal Advisors in the Office of Patent Legal Administration, by telephone at (703) 305-1622, by fax at (703) 305-1013, or by e-mail addressed to Jeanne.Clark@USPTO.gov or Robert.Clarke@USPTO.gov.

12/11/02  
[date]

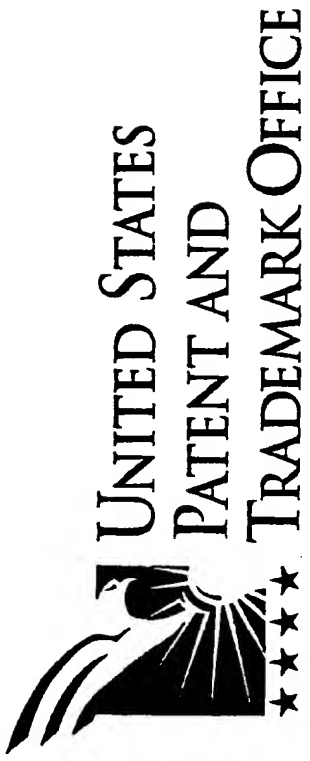
/s/  
Stephen G. Kunin  
Deputy Commissioner  
for Patent Examination Policy

<sup>1</sup> An original version of this Notice, signed on November 4, 2002, was posted on the Office's web site, and disseminated in paper copy form as a Pre-OG Notice as it was expected that the Notice would soon publish in the Official Gazette. In view of comments received, however, this revised version of the Notice additionally includes a clarification of Office policy in "(7) Final Rejection Practice" in Section IV of the Discussion portion, some further applicability notes in Examples 5 and 6 in Section V of the Discussion portion, and some minor edits. In addition, Item B of the Significant Provisions portion, the third paragraph of Section II of the Discussion portion and part (c)(ii) of "(4) Determine the appropriate § 102(e) date for each potential reference by following the guidelines below and examples set forth under Part V" in Section IV of the Discussion portion have been revised to note that the filing dates of international applications that designate the U.S. (which are filing dates in the U.S.) are only treated as prior art dates under 35 U.S.C. § 102(e) under certain circumstances. This revised Notice signed December 11, 2002, therefore, supercedes the original Notice.

<sup>2</sup> If the reference is a patent based on an International Application filed prior to November 29, 2000, § 102(e) prior to the AIPA is used to determine its § 102(e) prior art date.

<sup>3</sup> The amendments to § 102(e) were set forth in section 4505 of the AIPA, as amended by H.R. 2215. The amendments to § 374 were set forth in section § 4507 of the AIPA, as amended by H.R. 2215.

<sup>4</sup> The revision to 35 U.S.C. § 103(c) was made in § 4807 of the AIPA and is applicable only to applications filed on or after November 29, 1999.



# 35 U.S.C. §§ 102(e) and 374

as amended by

## H.R. 2215 (Technical Amendment Act)

Date enacted: 11/02/02

Date effective: 11/29/00

Prepared by:

Office of Patent Legal Administration (OPLA)

Robert J. Spar, Director

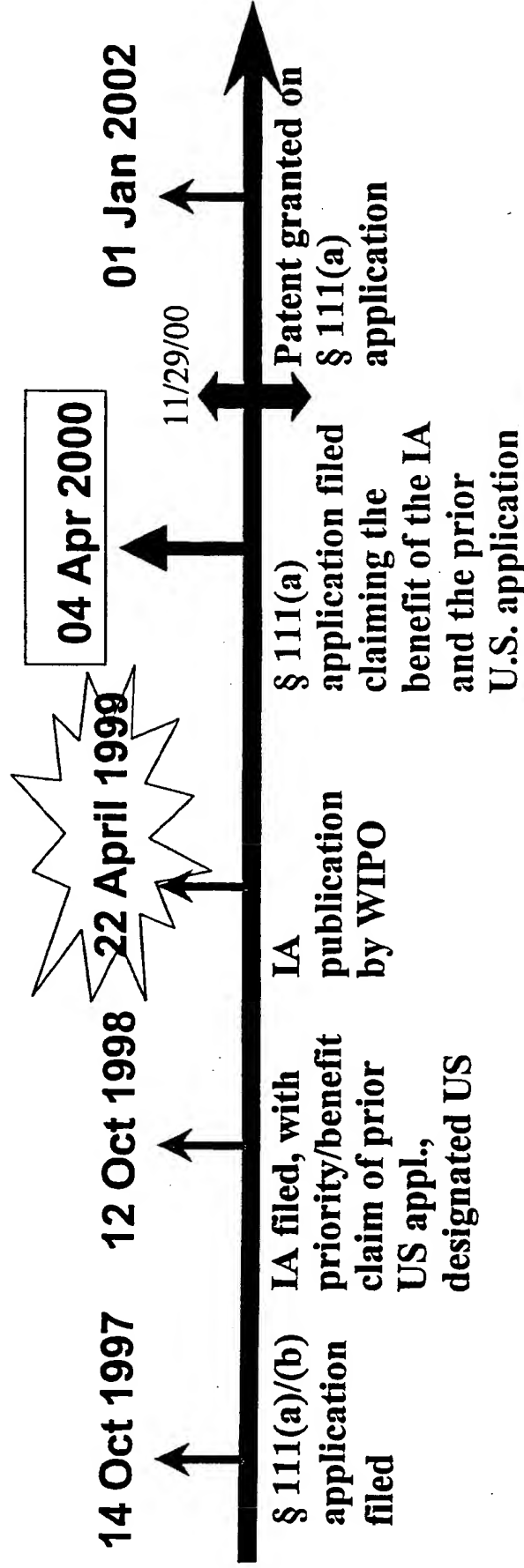
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**Ex. PSB: PATENT DERIVED FROM THE CONTINUATION OF AN IA WHICH CLAIMS PRIORITY / BENEFIT OF A U.S. APPLICATION**

**Sample Timeline – Guideline 5**



**§ 102(e)(2) date of the patent: 04 Apr 2000**

**Notes:**

- ✓ Patent cannot be applied as of the earlier filing date of the IA or the earlier filing date of the § 111(a)/(b) application.
- ✓ The best prior art date for the disclosure is the § 102(a) or (b) date (22 April 1999) of the WIPO publication of IA. The publication date can be determined by doing a family data search on the prior applications.